UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

HEARTLAND MEDICAL, LLC,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Cause No.: 4:17-cv-2873
	)	
EXPRESS SCRIPTS, INC.,	)	JURY TRIAL DEMANDED
	)	
Defendant.	)	

COMPLAINT FOR
DECLARATORY JUDGMENT AND DAMAGES

Plaintiff Heartland Medical, LLC ("Heartland Medical"), by and through its counsel of record, states the following for its Complaint against Defendant Express Scripts, Inc. ("ESI"), seeking declaratory relief and an award of damages:

NATURE OF THE ACTION

1. This is an action to recover damages arising out of ESI's wrongful withholding of over $1 million that ESI, one of the nation's largest pharmacy benefits managers, owes Heartland Medical, an independent pharmacy, as reimbursement for claims submitted for over-the-counter diabetic testing supplies. Heartland Medical lawfully and properly acquired and dispensed diabetic testing supplies to patients in ESI's network. Nonetheless, ESI deliberately conjured up pretextual reasons to deny payment to Heartland Medical, including by retroactively applying a newly-imposed Network Provider Manual provision and falsely claiming that the provision allowed ESI to withhold payments owed to Heartland Medical. To add insult to injury, ESI then terminated Heartland Medical from ESI's network, including its network serving patients covered under Medicare Part D in clear violation of the "any willing pharmacy" ("AWP") requirement codified in federal law, which mandates that any pharmacy willing to accept

reasonable and relevant terms be included in Medicare Part D pharmacy networks. As a result, Heartland Medical has lost not only the payments owed by ESI, but also its customers and future profits.

2. ESI apparently believes that it can get away with this egregious conduct due to its sheer power in the marketplace. But, as outlined below, ESI must be held accountable in this case for its clear breach of the parties' agreement, its tortious interference with Heartland Medical's business and customer relationships, its unjust withholding of money, and its flagrant disregard for the federal AWP mandate.

3. On June 17, 2016, ESI notified Heartland Medical that it was conducting an "investigative review" regarding all of Heartland Medical's purchases, returns, and credits from March 8, 2015 to June 2, 2016. ESI proceeded to demand—and Heartland Medical and its wholesalers supplied—comprehensive information regarding Heartland Medical's wholesalers and the medications and supplies Heartland Medical purchased from these wholesalers.[1]

4. Under the terms of ESI's Network Provider Manual ("Manual") that were in effect during the March 2015 to June 2016 time period, Heartland Medical did "retain all records in accordance with industry standards and applicable laws, rules, and regulations," and did "make these records available" upon ESI's request.

5. Notably, for the March 2015 to June 2016 time period, Heartland Medical maintained more information than what was then required by industry standards and any governing law, regulation, or policy, and it provided all of that information to ESI during the "investigative review." Heartland Medical and its wholesalers provided the records and

[1] Heartland provides a range of pharmacy services to its patients, including prescription drugs and over-the-counter medical supplies.

information to ESI demonstrating legitimate purchases of all products. This information should have put an end to the so-called "investigation."

6. Instead, ESI summarily rejected much of this documentation by taking the position that Heartland Medical had failed to purchase over-the-counter diabetic testing supplies from "authorized wholesalers," even though such term has no basis or agreed upon definition within applicable law and regulation. Further, as detailed herein, this ambiguous and arbitrary requirement referencing "authorized wholesalers" was adopted after the claims at issue were submitted. ESI further requested additional documentation such as proof of origination and lot number information—which was information Heartland Medical was not required to keep under industry standards or applicable federal or state law (and thus not required by the Network Provider Manual in effect at the time of those purchases), though it had done so anyway. But when Heartland Medical provided that information during the investigation, ESI rejected it.

7. Having arbitrarily rejected the information requested, ESI declared that it was recouping its payments for all supplies dispensed by Heartland Medical to ESI's members during the investigative period by withholding approximately $1,310,413.18 in payments for validly-dispensed claims submitted by Heartland Medical since that time. As if that was not enough, ESI terminated Heartland Medical from ESI's network effective February 24, 2017. Even before ESI's termination was effective, ESI sent letters to Heartland Medical's customers notifying them of the termination.

8. The underlying demand by ESI for information showing purchases from "authorized wholesalers" was baseless and unreasonable because no such requirements exist under applicable law or regulation, and ESI's own Manual did not reference such requirements until nearly two weeks after ESI commenced its investigation. Even more arbitrary was ESI's

rejection of the authenticating information that Heartland Medical provided during the investigation, including National Drug Code (NDC) numbers, lot numbers and information demonstrating the reputableness of its wholesalers. The fact that ESI attempted to impose these new requirements retroactively—and then rejected the very information it had (unreasonably) requested—suggests that ESI's real motive was to push Heartland Medical out of ESI's network, thus allowing ESI to hijack Heartland Medical's relationships with its customers.

9. ESI is incentivized to terminate independent pharmacies like Heartland Medical so that ESI can direct those pharmacies' patients to ESI's self-owned mail order pharmacy.

10. Tellingly, there has been no allegation that any customer complained about a product or its packaging, received an unsafe or counterfeit product, received a product intended for another market, or did not receive his or her diabetic testing supplies. Nor is there any indication that ESI was concerned enough about the authenticity of the products to contact the recipients to advise them to not use the products. ESI's termination of Heartland Medical from its network and its withholding of over $1 million is in violation of the parties' contract and applicable law, including the federal AWP mandate. Heartland brings this action to seek declaratory and compensatory relief from ESI's unlawful acts, and specifically, to compel ESI to comply with its contractual obligations, pay Heartland Medical the $1,310,413.18 that ESI has wrongfully "recouped," invalidate ESI's wrongful termination of the parties' contract, and allow Heartland Medical back into ESI's network.

11. In sum, ESI falsely and retroactively manufactured grounds for so-called claim discrepancies, then used the purported finding of discrepancies as a pretext to withhold money from Heartland and terminate Heartland, thereby forcing a competitor out of its network.

THE PARTIES

12. Plaintiff Heartland Medical is a limited liability company organized and existing under the laws of the State of Kansas, with its principal place of business in Lenexa, Kansas.

13. Defendant ESI is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business in St. Louis, Missouri.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction under 28 U.S.C. § 1332 because this action is between citizens of different states and because the amount in controversy, exclusive of interest and costs, exceeds $75,000.00.

15. Venue in the Eastern District of Missouri is proper under 28 U.S.C. § 1391, because the defendant's principal place of business is in this judicial district and because a substantial part of the events or omissions giving rise to the action occurred within this judicial district.

16. In addition, venue is proper pursuant to the Network Provider Manual, which is part of the agreement between Heartland Medical and ESI. The Network Provider Manual's "Dispute Resolution" section requires "[a]ll litigation between the parties . . . [to] be litigated in the U.S. District Court for the Eastern District of Missouri[.]"

HEARTLAND MEDICAL'S SERVICES TO DIABETIC PATIENTS

17. Heartland Medical is an independent pharmacy that supplies over-the-counter diabetic testing supplies to individuals with diabetes.

18. Heartland Medical purchases over-the-counter diabetic testing supplies from reputable wholesalers. These wholesalers have been in business for years and have served countless pharmacies throughout the nation.

19. Heartland Medical takes many steps to independently verify that the products it purchases are authentic and high quality.

a. For example, Heartland Medical only acquires supplies that contain valid NDC numbers and barcodes on boxes, contain a toll-free number for patients to call for any issues with their test strips, and are packaged and labelled in English.

b. Heartland Medical confirms the existence of valid NDC numbers and lot numbers when it receives products from its wholesalers, and further validates the authenticity of its products by confirming the existence of valid NDC numbers and lot numbers when its pharmacists supply products to patients. An NDC is a universal product identifier in the United States. A lot number is an identification number assigned to a particular quantity or lot of material from a manufacturer.

c. Heartland Medical carefully inspects all products that are received to ensure they are fully sealed and not expired.

d. Heartland Medical does not acquire or sell foreign-sourced or "suspect" over-the-counter diabetic testing supplies.

e. Heartland Medical does not acquire or sell over-the-counter diabetic testing supplies that are not FDA approved, not appropriately labeled, and/or not packaged for sale in the United States.

20. Between March 2015 and June 2017, Heartland Medical provided over-the-counter diabetic testing supplies to customers within ESI's network. ESI reimbursed Heartland Medical for claims submitted for the supplies, never questioning the reputation of Heartland Medical's wholesalers or the authenticity of the products provided to the customers. During this time period (as always), Heartland Medical only provided authentic and saleable supplies to its

customers. Upon information and belief, no customer complained to Heartland Medical about the quality or authenticity of any of the diabetic testing supplies dispensed during this time.

ESI'S ROLE AND INFLUENCE IN THE PHARMACY MARKET

21. ESI is the largest pharmacy benefit manager ("PBM") in the United States. PBMs like ESI administer the drug benefit portions of health plans for entities that pay for prescription drugs and medical supplies, including commercial insurance carriers and Medicare Part D plan sponsors. PBMs act as middlemen between these payors and everyone else in the market, including manufacturers and retailers. PBMs control the reimbursements for drugs and other pharmacy products, dispensing fees, and the ability of pharmacies such as Heartland to participate in the PBMs' networks. Manufacturers may also pay PBMs rebates and other fees that incentivize the PBM to steer their drugs and other products to the patients whose benefits the PBMs manage.

22. The PBM industry has consolidated and grown more powerful over the past several years. The three largest PBMs—ESI, CVS Health, and OptumRx—accounted for three-quarters of the United States prescription drug market in 2015, up from 49% in 2011.[2] ESI is the largest of the three, as it controls where more than one-third of Americans can fill their prescriptions.[3] ESI's 2016 revenue was roughly $100 billion.[4]

23. PBMs like ESI have been accused of colluding with drug manufacturers to the detriment of customers and other market participants. For example, diabetic patients recently

[2] *See* "Drugmakers Point Finger at Middlemen for Rising Drug Prices," The Wall Street Journal, October 3, 2016, available at http://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336 (last accessed December 13, 2017).

[3] *See* Health Strategies Group, "Pharmacy Benefit Managers" Research Agenda 2015, available at http://www.healthstrategies.com/sites/default/files/agendas/2015_PBM_Research_Agenda_RA_110714.pdf (last accessed December 13, 2017).

[4] *See* Express Scripts, Press Release: "Express Scripts Announces 2016 Fourth Quarter and Full Year Results," February 14, 2017, available at https://expressscriptsholdingco.gcs-web.com/news-releases/news-release-details/express-scripts-announces-2016-fourth-quarter-and-full-year (last accessed December 13, 2017).

filed a series of class action lawsuits against ESI, CVS Health, OptumRx, and manufacturers of diabetic testing supplies accusing the defendants of colluding to inflate prices for these products. The plaintiffs allege that the PBMs extract billions of dollars in price concessions from drug companies eager to secure spots on the PBMs' formularies (i.e., the rosters of approved drugs the PBMs maintain for their health plan clients). To do so, the drugmakers offer PBMs rebates for each prescription filled. The plaintiffs allege that test strips cost as little as eleven (11) cents per strip to manufacturer, but are often sold for one dollar or more per strip. Manufacturers artificially inflate the list prices for such strips in order to offer PBMs deeper rebates. The PBMs then earn profits by cashing in on the spread between the manufacturer's list price and the net price for a given product.

24. Independent pharmacies have filed lawsuits against ESI accusing the company of improperly terminating them from ESI's networks in order to steal their customers and profits. The allegations in these cases follow a typical trend. The complaints accuse ESI of instigating audits, during which ESI unearths minor issues of alleged non-compliance with the terms of ESI's policies and procedures. ESI then trumps these minor issues into so-called material breaches, which ESI then cites as justification for immediate termination. The real motivation for ESI's conduct, these complaints have alleged, is to steer the affected pharmacies' patients to its own wholly-owned pharmacy, so that it can capture the revenues from sales to the misappropriated patients.

25. Upon information and belief, ESI has become increasingly aggressive in its audits of pharmacies in its networks, improperly applying policies in order to maximize discrepancy and overpayment findings. As a result of these audit tactics, pharmacies have faced the loss of

millions of dollars in increased recoupments and/or network terminations from ESI based on newly-fabricated or non-material allegations of non-compliance.

26. For example, upon information and belief, ESI increasingly identifies its audits as "investigations," in attempt to invoke the "investigation procedures" section of the Network Provider Manual (rather than the "audit" section of the manual). Pursuant to the terms of the Network Provider Manual, "investigations" are intended as inquiries into suspected "fraud, waste or abuse," whereas "audits" are ordinary reviews of claims. By labeling an audit as an investigation, ESI attempts to circumvent the laws of more than thirty (30) states that regulate how PBMs conduct pharmacy "audits"—which were enacted in response to concerns that audits can largely be a money grab in which the PBMs look for reasons to deny claims. Indeed, many states have "pharmacy bill of rights"-type rules, which regulate pharmacy audits but contain exceptions for investigative activity.

27. Pharmacy participants have no meaningful input and/or opportunity to negotiate the terms of their contracts with ESI, and as such, the pharmacies have little or no recourse when ESI employs aggressive "audit" tactics. A pharmacy can challenge initial audit findings through ESI's internal appeals process, but the appeal is reviewed solely by ESI, and it is ESI alone, without any independent oversight, that ultimately decides whether to accept any of the substantiating documentation submitted by the pharmacy. The result is a process that is susceptible to abuse and manipulation.

28. The AWP requirements enacted by Congress in the 2003 Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") ensure that Medicare Part D plan sponsors and their intermediaries, including PBMs, cannot arbitrarily exclude pharmacies from serving Medicare beneficiaries. Specifically, the regulations implementing the MMA require

that Medicare Part D plan sponsors, and the PBMs such as ESI that maintain pharmacy networks on their behalf, agree to have a standard contract, containing reasonable and relevant terms and conditions of participation, that is accessible to pharmacies who are interested in joining the network; any pharmacy willing to agree to those reasonable and relevant terms and conditions must be permitted to participate as a network pharmacy. 42 C.F.R. § 423.505(b)(18). In contrast, ESI's tactics contravene both the letter and spirit of the AWP Mandate, as they hinder the policy of openness embodied in the Medicare Part D program's AWP requirements, harm competing pharmacies trying to meet the needs of their customers by mounting unreasonable barriers to market entry, and hurt patients and benefits payers nationwide by reducing pharmacy choice and inflating the end cost of needed medical supplies.

29. While ESI often touts patient safety as the motivation for conducting "investigations" like the one directed at Heartland Medical, ESI's own actions belie this platitude—particularly with regard to its arbitrary rejection of specified evidence of the authenticity of covered medical supplies. ESI's conduct demonstrates that patient safety and product integrity were merely a pretext for the investigation of Heartland Medical and had zero bearing on ESI's decision to fine and terminate the pharmacy.

ESI BEGINS TO EXERT PRESSURE ON DIABETIC SUPPLIERS

30. Upon information and belief, ESI began a concerted effort to limit the distribution of diabetic testing supplies within ESI's network in the middle of 2016. The apparent goal of this pressure was to drive competitors from the marketplace and to maximize control over the profits that ESI and manufacturers enjoy from the sale of such supplies.

31. On June 2, 2016, ESI's "Network Pharmacy Weekly" newsletter stated that ESI had been notified by a number of manufacturers of concerns about "gray market" diabetic testing

supplies. According to ESI's newsletter, the manufacturers indicated that they only sell their products through authorized sellers to combat gray market trade. The newsletter did not identify any of the authorized wholesalers or distributors but noted that, in the future, ESI would be requiring network participants to maintain documentation such as lot numbers and proof of payment to validate the authenticity of products purchased from so-called "unauthorized" sources.

32. Around the same time that ESI issued its newsletter, ESI began conducting sweeping "investigations" of independent pharmacies in its network that were dispensing diabetic testing supplies to customers.

33. Also around the same time, ESI amended its Network Provider Manual to create new and additional requirements on the records and information that must be maintained by providers that were dispending diabetic testing supplies.

ESI STRATEGICALLY AMENDS THE NETWORK PROVIDER MANUAL TO DEPART FROM EXISTING REGULATIONS

Statutory "Pedigree" Requirements Do Not Apply to OTC Diabetic Supplies

34. Applicable federal and state laws and regulations do not impose any "pedigree" or tracking requirement with regard to over-the-counter diabetic testing supplies.

35. In particular, the Prescription Drug Marketing Act of 1987, 21 U.S.C. § 353 ("PDMA"), the Drug Quality Security Act, Pub. L. No. 113-54 ("DQSA") (specifically Title II, known as the Drug Supply Chain Security Act), and their implementing regulations do not require maintenance of pedigree or tracking information for over-the-counter items, such as the diabetic testing supplies at issue in ESI's "investigation" of Heartland Medical. The PDMA applies to drugs that may only be dispensed based on a prescription, and it does not include over-the-counter medical supplies or other over-the-counter products, such as diabetic testing

supplies, within its provisions. 21 U.S.C. § 353(b)(1). Title II of the DQSA applies to "products," which is defined, in relevant part, as a "prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution)." 21 U.S.C. § 360eee(13). "Prescription drug" is defined as "a drug for human use subject to section 353(b)(1) of [the Food Drug and Cosmetics Act]." 21 U.S.C. § 360eee(12). Over-the-counter diabetic testing supplies, which do not require a prescription to dispense to patients, are not subject to the PDMA or DQSA. This is notwithstanding the fact that a PBM will not pay for such supplies unless a patient has a prescription for them.

The January 2015 Manual

36. In January 2015, ESI issued a revised Network Provider Manual.

37. The January 2015 Manual was in effect when Heartland Medical joined ESI's network. Heartland Medical was not given any opportunity to negotiate the terms of that Manual.

38. In relevant part, the January 2015 Manual's provision on "Required Records" in Section 5.1, stated:

> Network Provider must retain all records in accordance with industry standards and applicable laws, rules, and regulations (or for six (6) years, whichever is greater). Network Provider must make these records available to PBM and any applicable local, state, and federal regulatory authorities.
>
> Network Provider agrees to provide PBM with any and all information and documents requested relating to a Covered Service including, but not limited to: . . . .

39. The "Required Records" provision then listed roughly twenty (20) different categories of information or records that may be required. However, it is clear that not all of those categories are applicable to every single claim for a covered service.

40. One of those categories is "wholesaler and supplier invoices, proof of invoice payment, and pedigrees." The term "pedigrees" references information that was, in fact, not required by contemporaneous industry standards or applicable laws, rules, and regulations for over-the-counter diabetic testing supplies, like those purchased by Heartland Medical.

41. The January 2015 Manual also contained a "Counterfeit Reporting" provision in Appendix B to the Manual, which provided:

> Provider agrees it shall cooperate and coordinate with Express Scripts in implementing any counterfeit identification, investigation, tracking and reporting efforts undertaken by Express Scripts. Provider must notify Express Scripts in writing if it becomes aware that any counterfeit drugs have been provided to Members by Provider. Further, Provider represents and warrants (for itself and on behalf of its Pharmacies) that it (and its Pharmacies) purchase prescription drugs and supplies only from reputable wholesalers and/or manufacturers in accordance with the then prevailing industry standards.

42. Heartland has always purchased from reputable wholesalers in accordance with industry standards and applicable laws, rules and regulations and has had absolutely no reason whatsoever to believe that any counterfeit or gray market drugs (or other products) have ever been provided to ESI's patients.

The July 2015 Manual

43. In July 2015, ESI issued another revised Network Provider Manual. The July 2015 Manual was binding on Heartland Medical, though Heartland Medical was not given any opportunity to negotiate its terms.

44. The July 2015 Manual contains "Required Records" and "Counterfeit Reporting" provisions identical to the January 2015 Manual.

The January 2016 Manual

45. In December 2015, ESI issued a revised Network Provider Manual, which, upon information and belief, was effective on or around January 1, 2016. The January 2016 Manual

was binding on Heartland Medical, though Heartland Medical was not given any opportunity to negotiate its terms.

46. The January 2016 Manual contains "Required Records" and "Counterfeit Reporting" provisions that are identical to the January and July 2015 versions.

47. The January 2016 Manual was effective through June 30, 2016.

The July 2016 Manual

48. On July 1, 2016, ESI again amended its Network Provider Manual. The July Manual did not take effect any earlier than July 1, 2016.

49. In the July 2016 Manual, ESI expanded its "General Claims Submissions Policies" in Section 2.4 to add several new distinct sub-requirements, including this new provision (emphasis added in bold and underline):

> Network Provider will validate the authenticity of all products purchased and fully vet their wholesalers and suppliers. **Network Provider will be required upon request to furnish pedigree or proof of origin of products regardless of whether the products submitted are prescription drugs or DME products, including but not limited to diabetic supplies, testing strips, lancets and glucometers**. In the case of DME products, Network Provider is responsible for ensuring products are purchased from suppliers that are authorized by the manufacturer to distribute these products.

50. Prior to July 1, 2016, there were no requirements for pedigree or proof of origination imposed by the Network Provider Manual applicable to over-the-counter diabetic testing supplies. The fact that ESI added this new provision effectively confirms that the Provider Manual did not previously contain such requirements.

51. In addition, the July 2016 Manual specifically expanded the "Required Records" provision in Section 5.1 to expressly cover diabetic testing supplies. The expanded provision now states (added language emphasized in bold):

> Wholesaler and supplier invoices, proof of invoice payment, and pedigrees. **When the wholesaler or supplier is not recognized by the manufacturer as an authorized wholesaler or supplier of DME products, including but not limited to diabetic supplies, testing strips, lancets, and glucometers, the supplier's invoices will be rejected. When an authorized wholesaler listing does not exist for DME products, proof of product origin, supplier proof of purchase from manufacturer, product lot numbers and additional documentation will be required at PBM's discretion.**

52. The July 2016 Manual did not make any changes to the "Counterfeit Reporting" provision in Appendix B.

ESI INITIATES AN INVESTIGATIVE REVIEW OF HEARTLAND MEDICAL AND ACTS IN BAD FAITH

53. By letter dated June 17, 2016—approximately two weeks prior to ESI's issuance of the July 2016 Manual—ESI informed Heartland Medical that it had identified the pharmacy for "investigative review" and was seeking to verify inventory purchases to support roughly fourteen (14) months' worth of claims Heartland Medical had submitted to ESI. Specifically, ESI demanded that Heartland Medical forward its letter to each of Heartland Medical's wholesalers and ask that each provide a summary of all purchases, returns, and credits from March 8, 2015 through June 2, 2016. ESI's letter expressly requested the following information from Heartland's wholesalers: NDC, purchase/invoice dates, return dates (if applicable), invoice numbers, description/drug names, GCNs, items sizes, item forms, total quantity shipped, total quantity returned or credited, and grand total quantity shipped. ESI asked that wholesalers submit this information no later than July 5, 2016. ESI also required Heartland Medical to complete an attestation listing the "wholesalers/suppliers/any other sources of drug products that service Heartland Medical" by June 27, 2016.

54. In an effort to cooperate with ESI, Heartland Medical forwarded the June 17, 2016 letter from ESI to its wholesalers/suppliers. Heartland Medical also timely submitted, and

then revised and resubmitted, the attestation listing the "wholesalers/suppliers/any other sources of drug products that service Heartland Medical."

55. Heartland Medical's wholesalers/suppliers responded to ESI as requested in or around late June 2016.

56. On July 1, 2016—almost two weeks after initiating its investigation of Heartland Medical and almost four weeks after the end of time period subject to the investigation—ESI issued the July 2016 Manual with amendments to the "General Claims Submission Policy" and "Required Records" provisions that purportedly now require providers like Heartland Medical to maintain new and additional information for over-the-counter diabetic testing supplies.

57. On or about July 12, 2016, ESI sent another letter to Heartland Medical, indicating that it was requiring additional documentation from seven different wholesalers. ESI claimed that it had "identified invoices submitted for One Touch, Precision, FreeStyle, and Accu-Check products"—which are over-the-counter diabetic testing supplies—and that it had learned that the wholesalers "are not an authorized distributor of these products, according to Abbott, Johnson & Johnson, and Roche." ESI then requested "both proof of the products [sic] origination and lot numbers" for the products purchased from these wholesalers, "in an effort to substantiate the legitimacy of the products."

58. ESI's reference to "authorized distributor[s] of these products" was a clear reference to ESI's new Network Provider Manual provision, put in effect roughly twelve (12) days earlier. These new provisions of the Provider Manual were not in effect when Heartland Medical made the purchases that ESI was "investigating."

59. Further, ESI's July 12, 2016 letter provided no instruction or guidance as to how Heartland Medical was to determine whether a specific wholesaler was an "authorized

distributor." Neither the letter, nor the Network Provider Manual provides a definition of this term.

60. Heartland Medical contacted its wholesalers and diligently provided ESI with all available information about the purchased supplies, including lot number information that Heartland Medical had maintained even though not required to do so by applicable law or by any contract term then in effect.

61. The wholesalers identified in ESI's July 12, 2016 letter submitted additional responses to ESI on or about July 19 and 20, 2016. The wholesalers' submissions explained that they were fully insured and licensed under applicable law and had been reputably serving the independent pharmacy market for years. The wholesalers also told ESI that they did not repackage, alter or make any false statements regarding the supplies that they sold to Heartland Medical.

62. Heartland Medical subsequently contacted ESI's auditor by telephone and offered to provide ESI with documentation establishing proof of origination, including lot numbers and NDC numbers, for the products reimbursed by ESI. As Heartland Medical explained to ESI, Heartland Medical checked for and confirmed the existence of valid NDC numbers and lot numbers when it received products from its wholesalers and again when those products were dispensed to patients. An NDC is a universal product identifier in the United States. A lot number is an identification number assigned to a particular quantity or lot of material from a manufacturer.

63. By email dated July 29, 2016, Heartland Medical submitted to ESI a spreadsheet listing each of the products sold to customers and reimbursed by ESI in 2015, which included the

date of transaction, lot number, and NDC number. Heartland Medical also submitted photographs of samples of the products at issue.

64. As part of its efforts to cooperate with ESI, Heartland Medical requested that ESI provide a list of approved or authorized vendors of the diabetic testing supplies at issue, in order to avoid similar audits in the future. ESI never responded or provided the requested information.

65. On or about November 1, 2016, ESI notified Heartland Medical that it had identified so-called "discrepancies" totaling $1,094,019.30. Specifically, ESI identified $1,093,013.42 in "purchase verification discrepancy findings" relating to diabetic testing supplies and $1,005.88 in "prescription discrepancy findings."

66. ESI's November 1, 2016 letter stated that Heartland Medical would have until November 15, 2016 to contest the discrepancies.

67. ESI also stated, in a separate letter dated November 1, 2016, that it would withhold reimbursement checks due to Heartland Medical, pending the final resolution of the matter.

68. By letters dated November 15, 2016 and January 19, 2016, Heartland Medical contested the findings in ESI's November 1, 2016 letter. Heartland Medical pointed out that the January 2015 Manual required only that Heartland Medical "retain all records in accordance with industry standards and applicable law, rules, and regulations." Pedigree information for diabetic testing supplies was not required to be kept under industry standards or applicable law, rules, and regulations during the period in question. Accordingly, Heartland Medical alerted ESI that any attempt by ESI to recoup money as a result of its investigation would be improper and without basis under the Provider Manual or applicable law.

69. ESI ignored federal law and its own Manual and did not accept Heartland Medical's arguments as to why ESI's findings were without merit. Instead, ESI withheld $1,310,413.18 from Heartland Medical through supposed "recoupments." ESI's withholding amount included the $1,094,019.30 that ESI had identified during its investigation, plus a fifteen percent (15%) penalty of $164,102.90, plus an additional unspecified recoupment of $53,965.62.

70. Despite ESI's wrongful withholding of $1,310,413.18 from Heartland Medical, the patients retained the diabetic testing supplies. Notably, ESI did not allege or claim that any customer complained about or did not receive his or her diabetic testing supplies. ESI did not allege or conclude that Heartland Medical distributed any gray market testing supplies. Nor did ESI state that it was concerned enough about the authenticity of the products to contact the recipients to advise them to not use the products, or that ESI was returning the fees it had earned from its own customers for managing the dispensation of the supplies to Heartland Medical's customers.

71. In Heartland Medical's correspondence dated January 19, 2017, it disputed the final alleged discrepancies, ESI's reliance on the failure to provide proof of origination as a basis to dismiss purchases and ESI's retroactive application of provisions of the 2016 Network Provider Manual that were neither anticipated nor in effect during the audit timeframe. Heartland Medical submitted this correspondence in accordance with the Dispute Resolution provisions stated in Appendix B at page 258 of the Network Provider Manual.

ESI USES ITS SO-CALLED INVESTIGATIVE FINDINGS TO JUSTIFY THE TERMINATION OF HEARTLAND MEDICAL'S FROM ITS NETWORK

72. On February 10, 2017, ESI sent Heartland Medical written notice that ESI was terminating Heartland Medical from ESI's network effective February 24, 2017. The letter stated that ESI's purported "Pharmacy Disciplinary Action Committee" had voted to terminate

Heartland Medical for cause in accordance with Appendix B of the Provider Manual. It does not identify the reason or "cause" for the termination.

73. The February 10, 2017 letter provided no background concerning this Committee, including the makeup of the Committee or any evidence of any meeting, discussion, or vote or that took place from this so-called Committee. Heartland Medical was not provided an opportunity to address this alleged Committee prior to its unilateral determination that Heartland Medical had engaged in conduct warranting termination for cause. Nor did the February 10 letter provide or discuss any of the Committee's findings, if there were any, backing up the Committee's alleged determination.

74. ESI's February 10 letter contained the following quotation from the "Immediate Termination" subprovision of the Termination section in Appendix B of the Provider Manual:

> **Immediate Termination**. PBM shall have the right to immediately terminate this Agreement upon written notice to Network Provider in the event that . . . (ii) Network Provider submits a fraudulent prescription drug claim or any information in support thereof; (iv) Network provider routinely fails to designate on its claims submissions and/or supporting documents the information required by PBM or fails to comply with PBM's policies and procedures including, but not limited to, the Provider Manual and/or quality assurance and/or utilization review procedures; [sic] and (xiii) a determination is made by PBM that Network Provider (or any Pharmacy) failed to document purchases of prescription drugs sufficient to support its claims for reimbursement to PBM . . .

75. The February 10 letter did not contain any further explanation of the basis for ESI's decision to terminate Heartland Medical for "cause." If ESI's citations to Sections (ii), (iv), and (xiii) of the Immediate Termination provision were meant to imply that Heartland Medical had violated those provisions of the Provider Manual, such implication was without basis or merit.

76. Heartland Medical did not "submit a fraudulent prescription drug claim or any information in support thereof."

a. First, Heartland Medical did not submit any "prescription drug claim[s]" (or any information in support thereof) to ESI related to the discrepancies alleged. The products at issue were over-the-counter diabetic testing supplies, not prescription drugs.

b. Second, Heartland Medical did not engage in any type of fraud, and ESI has no basis to conclude otherwise. Heartland Medical provided ESI with information on Heartland Medical's wholesalers, who in turn responded to ESI's inquiries. ESI cited no evidence whatsoever in any of these responses that would support the conclusion that Heartland Medical engaged in fraud.

77. Heartland Medical did not "routinely fail[] to designate on its claims submissions and/or supporting documents the information required by PBM or fail[] to comply with PBM's policies and procedures including, but not limited to, the Provider Manual and/or quality assurance and/or utilization review procedures." As detailed above, Heartland Medical's employed a rigorous compliance policy, including purchasing the highest quality products from reputable domestic wholesalers, validating NDC and lot numbers, and ensuring that products were fully sealed and unexpired prior to sale to customers.

78. Similarly, Heartland Medical did not "fail[] to document purchases of prescription drugs sufficient to support its claims for reimbursement to PBM." The audit discrepancies involved Heartland Medical's purchase and sale of over-the-counter diabetic testing supplies, not prescription drugs. Moreover, Heartland Medical's wholesalers provided ESI documentation of purchases that were more than sufficient to support all claims for reimbursement submitted to ESI. In addition, although not required to do so by ESI's then-applicable policies and procedures, Heartland Medical did keep track of lot numbers origination information, which was provided to ESI as further support for the purchase documentation provided. Heartland Medical

provided a detailed spreadsheet documenting Heartland Medical's purchases to ESI during its audit. ESI refused to accept or consider this information during and after its audit.

79. After receiving ESI's February 10, 2017 termination notice, Heartland Medical once again objected to ESI's proposed grounds for termination. ESI responded by email on February 23, 2017. Tellingly, ESI did not attempt to rely on its prior references to pedigree documentation or purchases from authorized distributors. Instead, for the very first time, ESI artfully and incompletely quoted the "Required Records" provision in Section 5.1 of the Provider Manual, leaving out the first two sentences which make clear that Heartland Medical must "retain all records for the greater of six (6) years or in accordance with industry standards and applicable laws, rules, and regulations," that it is "these" records that Heartland Medical must provide to ESI, and that the ensuing categories of documents are clearly subject to this language.

80. ESI's February 23 email also cited Section 2.14 of the Provider Agreement on "Counterfeit Reporting" (identical to the "Counterfeit Reporting" provision in Appendix B of the Manual), in which Heartland Medical affirms that it "purchases prescription drugs and supplies only from reputable wholesalers and/or manufacturers."

81. Indeed, Heartland has always warranted that it purchases from reputable wholesalers and continues to affirm that fact.

82. ESI's February 23 email also cited the Network Provider Manual's generic provision on "Credentialing Standards" in Section 1.2, in which Heartland Medical broadly agreed that, as a Network Provider, it would provide ESI "with all documentation and other information needed to comply with and/or demonstrate compliance with [ESI's] programs, protocols, policies and procedures." Heartland has provided, either directly or through its wholesalers, more than sufficient information and records to demonstrate the authenticity of its

purchases, the validity of its claims, and its compliance with the version of the Manual in effect at the time the claim was submitted.

83. ESI's citation to these new sections is consistent with a recognition that ESI's previous citations to the July 2016 Network Provider Manual were improper and inapplicable to the claims at issue.

84. Regardless, the sections of the Network Provider Manual and Provider Agreement simply require Heartland Medical to purchase products from reputable wholesalers and to retain all records in accordance with industry standards and applicable laws, rules, and regulations. Heartland Medical has always done so, and provided the documentation to establish that it did so with respect to the purchases reviewed in ESI's so-called investigation.

85. Accordingly, neither Section 5.1 of the Provider Manual nor Section 2.14 of the Provider Agreement provide a valid basis for ESI's wrongful termination of Heartland Medical under the Immediate Termination provision cited in ESI's February 10, 2017 termination notice.

86. Like ESI's unjustified withholding of over $1 million, ESI's illegal termination of Heartland Medical from its network is nothing more than an brazen attempt to stymie competition, to divert Heartland Medical's patients to ESI's self-owned pharmacy, and to unjustly enrich ESI at Heartland Medical's expense. Fundamentally, from the time Heartland Medical joined the ESI network March 31, 2015 until it was prematurely terminated, it operated in compliance with the Provider Agreement and then-effective Manual and it served ESI's customers well-vetted products without incident or complaint. ESI has since found a way essentially to avoid paying for the vast majority of services Heartland Medical provided to ESI's patients by "recouping" payments between March 2015 and June 2016 and charging penalty fees to boot.

COUNT ONE – BREACH OF CONTRACT

87. Plaintiff repeats and reiterates each and every allegation set forth in the paragraphs 1 through 86 of this Complaint as if set forth herein.

88. Heartland Medical entered into a valid, binding contract with ESI, which consisted of the Pharmacy Provider Agreement and the Network Provider Manual.

89. At all times relevant to this dispute, Heartland Medical complied with all of the material terms and conditions of the contract.

90. ESI breached the contract by terminating it "for cause" when ESI had no valid cause to do so.

91. ESI also violated the contract by withholding funds, in the amount of $1,310,413.18, from Heartland Medical based upon alleged violations of terms and conditions not contained in the contract.

92. ESI was required, under the contract, to reimburse Heartland Medical for validly-submitted claims. By failing to do so, and instead withholding $1,310,413.18 in payments as an alleged "recoupment" following its so-called investigation, ESI breached the contract.

93. ESI's attempt to treat the parties' contract as a one-sided agreement, with ESI imposing unreasonable requirements and/or terminating the contract without valid cause at its whim, is contrary to the public policy established by Congress in MMA since 2003. That law, among other laudable aims, seeks to ensure that Medicare Part D sponsors and their intermediaries, which include ESI and the Part D plans whose benefits ESI administers as a PBM, are not able to arbitrarily exclude pharmacies from servicing Medicare beneficiaries.

94. Specifically, MMA regulations require all PBMs, including ESI, "[t]o agree to have a standard contract with reasonable and relevant terms and conditions of participation

whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." 42 C.F.R. § 423.505(b)(18). *See also* 42 U.S.C. § 1395w-104(b)(1)(A).

95. Federal law thus requires that any willing pharmacy that meets a pharmacy network's reasonable and relevant terms and conditions should be able to participate in such a network.

96. At all times up until ESI's wrongful termination, Heartland Medical met all reasonable and relevant terms and conditions for participation in ESI's network.

97. At least some of the customers who received the diabetic testing supplies included in ESI's "investigation" of Heartland Medical were Medicare beneficiaries.

98. In addition to violating the clear terms of the contract, ESI's termination of Heartland Medical from its network violates the Any Willing Pharmacy mandates in 42 C.F.R. § 423.505(b)(18) and 42 U.S.C. § 1395w-104(b)(1)(A).

99. As a direct and proximate result of ESI's breaches, Heartland Medical has suffered and will continue to suffer substantial monetary damages.

COUNT TWO – UNJUST ENRICHMENT

100. Plaintiff repeats and reiterates each and every allegation set forth in paragraphs 1 through 99 of this Complaint as if set forth at length herein.

101. Heartland Medical has conferred a benefit upon ESI by way of filling prescriptions in ESI's network.

102. ESI has recouped more than the full value of claims related to the diabetic testing supplies from Heartland Medical.

103. Critically, Heartland Medical's customers at all times received the prescribed diabetic testing supplies.

104. ESI's recoupment of more than the full value of claims related to diabetic testing supplies that Heartland Medical provided to patients, despite the fact that the customers at all relevant times received, retained, and/or otherwise benefited from the diabetic and supplies, is improper and constitutes unjust enrichment.

105. ESI has been unjustly enriched at Heartland Medical's expense.

106. As a direct and proximate result of ESI's unjust enrichment, Heartland Medical has suffered and continues to suffer substantial monetary damages.

COUNT THREE – BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

107. Plaintiff repeats and reiterates each and every allegation set forth in paragraphs 1 through 106 of this Complaint as if set forth herein.

108. In every contract executed under Missouri law, there is an implied covenant of good faith and fair dealing.

109. The contract between ESI and Heartland Medical contains an implied covenant of good faith and fair dealing and is subject to same.

110. ESI has violated the implied covenant of good faith and fair dealing by recouping money from Heartland Medical without any legal basis in the contract and/or federal or state laws or regulations.

111. Specifically, ESI recouped $1,310,413.18 from Heartland Medical based on alleged violations of terms not contained within the contract. As set forth herein, ESI had no contractual basis for taking the money from Heartland Medical.

112. Furthermore, ESI recouped $1,310,413.18 from Heartland Medical despite the fact that Heartland Medical complied with all applicable contractual provisions, as well as federal and state laws and regulations.

113. ESI's lack of good faith and fair dealing is evidenced by ESI's purported termination of the contract "for cause," even though ESI had no valid cause to do so.

114. ESI's lack of good faith and fair dealing is further evidenced by ESI's failure to comply with the federal Any Willing Pharmacy requirements, which require ESI to have a standard contract with reasonable terms to allow any willing pharmacy to access and participate in ESI's network. ESI failed to comply with these requirements when it improperly terminated Heartland Medical from its network based on unreasonable, irrelevant, and/or nonexistent contract terms.

115. In taking the actions described herein, ESI has exceeded the limits of reasonableness and violated the covenants of good faith and fair dealing.

116. By breaching the implied covenant of good faith and fair dealing as described herein, ESI has deprived Heartland Medical of the benefit of its bargain.

117. As a direct and proximate result of ESI's actions in breaching the implied covenant of good faith and fair dealing, Heartland Medical has suffered and will continue to suffer significant damages.

COUNT FOUR – TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS

118. Plaintiff repeats and reiterates each and every allegation set forth in paragraphs 1 through 117 of this Complaint as if set forth herein.

119. Heartland Medical has a valid business relationship with its customers.

120. ESI had actual knowledge of the relationship between Heartland Medical and these customers. As part of the process of seeking reimbursement for the prescriptions Heartland Medical filled, Heartland Medical necessarily provided ESI information about its continuing business relationship with each customer.

121. Upon information and belief, ESI has communicated with customers of Heartland Medical regarding Heartland Medical's purported termination from the network and the fact that Heartland Medical is no longer an authorized "in-network" provider. Upon information and belief, ESI also makes known that it provides mail-order services and that ESI is able to service the customers' ongoing prescription needs.

122. Upon information and belief, ESI communicated with patients of Heartland Medical with the intent and desire to misappropriate Heartland Medical's patients who are ESI members and to induce them to transfer their prescription services to ESI's own mail-order pharmacy.

123. Upon information and belief, ESI is intentionally interfering with Heartland Medical's customer relationships by inducing the customers to terminate their relationship with Heartland Medical and to transfer their prescriptions to ESI and/or other pharmacies.

124. ESI's interference is intentional and unjustified. ESI has used pretextual reasons to wrongfully terminate the Agreement.

125. As a result of ESI's intentional and unjustified interference, Heartland Medical has suffered and will continue to suffer significant actual and consequential damages.

COUNT FIVE – DECLARATORY JUDGMENT

126. Plaintiff repeats and reiterates each and every allegation set forth in paragraphs 1 through 125 of this Complaint as if set forth herein.

127. Neither the PDMA, the DQSA, nor any other federal or state law or regulation requires a pharmacy such as Heartland Medical to purchase inventory from specific "authorized" wholesalers or maintain pedigree or tracking information regarding over-the-counter medical supplies or other over-the-counter products, such as diabetic testing strips or supplies.

128. Prior to July 1, 2016, the contract did not reference "authorized wholesalers" and required pharmacies to retain all records in accordance with industry standards and applicable laws, rules, and regulations. Neither industry standards nor applicable laws, rules and regulations require Heartland Medical to maintain pedigree or tracking information regarding over-the-counter medical supplies or other over-the-counter products, such as diabetic testing supplies.

129. Despite the fact that applicable laws and regulations did not require pharmacies such as Heartland Medical to maintain pedigree or tracking information regarding diabetic testing strips or supplies and despite the fact that the contract similarly did not require maintenance of this information," ESI arbitrarily rejected documentation from legitimate wholesalers and retroactively imposed its vague and unilateral July 1, 2016 amendment of the contract on Heartland Medical for the time period of March 8, 2015 through June 1, 2016.

130. Despite ESI's wrongful conduct in attempting to interfere with Heartland Medical's selection of wholesaers and retroactively applying ambiguous new requirements, Heartland Medical did retain and in fact provided proof of origin information regarding the diabetic testing strips and supplies at issue.

131. ESI's termination of Heartland Medical is wrongful and based on improper immaterial requirements and plainly pretextual reasoning.

132. Based on ESI's termination of Heartland and improper withholding of Heartland Medical's funds, an actual, present, and justiciable controversy has arisen between Heartland Medical and ESI concerning ESI's practices and conduct, all of which are in blatant disregard of federal and state law and regulations.

133. ESI's termination of Heartland Medical from its network violates the Any Willing Pharmacy mandates in 42 C.F.R. § 423.505(b)(18) and 42 U.S.C. § 1395w-104(b)(1)(A).

134. Heartland Medical is entitled to a declaration that ESI's practices and conduct in retroactively imposing its unilateral July 1, 2016 amendment of the contract regarding pedigree information are unlawful, violate the terms and conditions of the contract, and violate the Any Willing Pharmacy requirements of federal law.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff Heartland Medical, LLC demands a trial by jury as to all claims and all issues properly so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Heartland Medical, LLC requests the Court enter judgment in its favor and against Defendant Express Scripts, Inc. as follows:

A. Directing that ESI reinstate Heartland Medical as an authorized participating provider in ESI's network;

B. Awarding damages to Heartland Medical in an amount according to the proof at trial, including, but not limited to, payment of the $1,310,413.18 wrongfully "recouped" by ESI plus all damages that Heartland Medical has suffered through its inability to participate in ESI's network since ESI's wrongful termination;

C. Awarding declaratory, equitable, and/or monetary relief as appropriate for the causes of action alleged herein;

D. Awarding pre-and post-judgment interest;

E. Awarding treble and/or exemplary damages; and

F. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

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